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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,213	11/22/2004	Suzanne Margaret Price	114.1007	5907

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,213	PRICE, SUZANNE MARGARET	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *10,11 and 20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed October 15, 2007. Applicants' arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

Election/Restrictions

2. This application contains claims 10, 11 and 20-22 drawn to an invention nonelected with traverse in the reply filed on March 12, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. Claims 1-9 and 12-19 have been examined herein. It is noted that claim 8 has been examined only to the extent that the claim reads on the elected invention of methods wherein the pretreatment is an enzymatic pretreatment.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 4 and 14 are indefinite over the recitation of "particularly well adapted for amplification via PCR." This phrase is not clearly defined in the specification and there is no art recognized definition for this phrase. Further, it has been held that the

recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. It is unclear as to whether unclear as to whether a contaminating nucleic acid that is particularly adapted for amplification is distinct from a nucleic acid that is merely adapted for amplification or from any other contaminating nucleic acid. Accordingly, one of skill in the art would not be able to determine the meets and bounds of the claimed subject matter.

Response to Remarks:

In the response, Applicant's traversed this rejection by pointing to page 5, lines 14-20 of the specification as teaching that the phrase "particularly well adapted for amplification via PCR" is defined as being "when the contaminating nucleic acid is free or substantially free from other cell components."

However, page 5 of the specification in fact states:

> When the contaminating nucleic acid is free or substantially free from other cell components it may be in a form that is particularly well adapted for amplification. via PCR or some other amplification process that is used in forensic analysis. One particular example of this type of contaminating nucleic acid is an amplicon derived from a PCR or another DNA amplification process and in particular a degradation resistant amplicon that has been specifically designed to persist at a site or in a sample. Synthetic DNA, RNA or PNA may also be used.

Accordingly, there is no clear teaching in the specification defining the phrase "particularly well adapted for amplification via PCR" as being limited to a contaminating nucleic acid that is free or substantially from other cell components. Rather, the specification teaches only that an example of a nucleic acid that is free or substantially free from other cell components is a nucleic that is adapted for amplification. Such a

teaching does not apprise one of the meaning of the phrase "particularly well adapted for amplification."

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker (EP 0585660; cited in the IDS).

Walker teaches a method for analyzing a nucleic acid sample obtained from a site wherein the method comprises: i) pretreating the nucleic acid sample with a single-strand specific exonuclease to remove or inactivate contaminating nucleic acids obtained from the site; and ii) amplifying the pretreated sample to thereby analyze the nucleic acid sample (see, e.g., page 2, lines 24-34 and page 4, lines 43-46). In the method of Walker, the step of treating the nucleic acid sample with a single-strand specific exonuclease constitutes a step of pretreating the sample.

Regarding claim 2, in the method of Walker, the nucleic acid is DNA (see, e.g., page 4, lines 3-15 and Example 2).

Regarding claim 3, the contaminating nucleic acid is considered to be well adapted for amplification via PCR since the contaminating nucleic acid may be amplified and may be the products (amplicons) of previous amplification reactions (see, e.g. page 2, lines 7-13).

Regarding claim 4, Walker teaches that the contaminating nucleic acid may be an amplicon from a previous PCR (see, e.g. page 2, lines 7-13).

Regarding claim 5, the contaminating nucleic acid is considered to be degradation resistant since DNA is substantially more stable than other molecules and is resistant to many enzymes, such as RNases.

Regarding claim 6, the contaminating nucleic acid is considered to be synthetic since nucleic acids that have been synthesized by some process such as an amplification process constitute synthetic nucleic acids.

Regarding claim 7, the method of Walker is one in which the pretreatment preferentially removes or inactivates nucleic acids produced by other amplification processes and thereby removes or inactivates nucleic acids that are free or substantially free of other cell components.

Regarding claims 8 and 9, the pretreatment step of Walker comprises treating the nucleic acid sample using an exonuclease (page 2, lines 24-30).

Regarding claim 12, Walker (page 2, lines 40-53) teaches that following the pretreatment step, the nucleic acid sample may be analyzed by any amplification method, including the method of PCR.

Response to Remarks:

In the response, Applicant's traversed this rejection by stating that the specification defines a 'contaminating nucleic acid' as a "nucleic acid that has been introduced to a site or a sample to confound future analysis of target nucleic acids present at the site or in the sample." Applicants assert that Walker is concerned only

with laboratory-derived contamination of prepared nucleic acid samples. This argument has been fully considered but is not persuasive. In the method of Walker, the sample is contaminated with laboratory derived nucleic acids. This type of nucleic acid meets the limitations of the claims since such a nucleic has been introduced into the sample in the laboratory and confounds future analysis of the sample.

Applicants assert that the method of Walker would be detrimental to the detection and removal of amplicon contamination where the DNA profile was determined by the use of single nucleotide polymorphisms as used in forensic studies. This argument has also been fully considered but is not persuasive because it is not directed to limitations recited in the claims. In particular, the present claims do not require detecting and removing an amplicon in a method of DNA profiling that uses SNPs for forensic studies.

The response argues that the method described by Walker uses only single-strand specific exonuclease agents for the removal of contaminating nucleic acids. It is argued that such enzymes would have limited utility in preventing contamination of the type identified in the current application as amplicons are currently double stranded. This argument is also not persuasive because the claims are not limited to methods in which the pretreatment is performed using an enzyme that removes or inactivates nucleic acids that are in a double-stranded form. Rather, the claims encompass the removal or inactivation of any nucleic acid. Further, the present claims are not distinguishable over the method of Walker since the present claims encompass the use of any "enzymic treatment" and thereby encompass the use of the single-strand specific exonucleases of Walker.

6. Claims 1-3, 5, 6, 8, 9, and 12-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Miwa (U.S. Patent No. 4,514,502).

Miwa teaches a method for analyzing a nucleic acid sample obtained from a site wherein the method comprises: i) pretreating the nucleic acid sample with a RNase to remove or inactivate contaminating nucleic acids obtained from the site; and ii) analyzing the pretreated nucleic acid sample (see, e.g., col. 6, lines 56-68 through col. 7, lines 1-6 and 48-51). In the method of Miwa, the step of treating the nucleic acid sample with RNase constitutes a step of pretreating the sample to remove or inactivate contaminating RNA.

Regarding claim 2, in the method of Walker, the contaminating nucleic acid present in the sample is RNA (see, e.g., col. 6, lines 56-68 through col. 7, lines 1-6).

Regarding claims 3 and 14, the contaminating nucleic acid is considered to be well adapted for amplification since RNA can be readily amplified by reverse transcription.

Regarding claim 5, the contaminating nucleic acid is considered to be degradation resistant since RNA is resistant to many enzymes, such as DNases.

Regarding claim 6, the contaminating nucleic acid is considered to be synthetic since RNA present in a bacterial cell has been synthesized.

Regarding claims 8 and 9, the pretreatment step of Miwa comprises treating the nucleic acid sample using the enzyme RNase (col. 6, lines 68-col. 7., line 1).

Regarding claim 12, it is a property of the resulting nucleic acid that it can be analyzed by any amplification method, including the method of PCR. It is noted that the

claim does not in fact require performing an active step of amplifying the isolated nucleic acid.

Regarding claims 13-19, Miwa (col. 6, lines 56-68) teaches that the bacterial cell is first lysed prior to treatment with RNase. Accordingly, the pretreatment steps of Miwa include removing cell bound nucleic acids from a cell by exposing the nucleic acids in the cells using a lysing procedure and then removing the nucleic acids using an RNase pretreatment step.

Regarding claim 15, the contaminating RNA is of bacterial origin since it is present in a bacterial cell.

Regarding claim 16, the bacterial cell has been engineered to carry a multicopy plasmid containing at least one amplicon (see col. 2, lines 22-25; col. 3, lines 3-50; col. 4, lines 38-45).

Response to Remarks:

In the response, Applicant's traversed this rejection by again stating that the specification defines a 'contaminating nucleic acid' as a "nucleic acid that has been introduced to a site or a sample to confound future analysis of target nucleic acids present at the site or in the sample." Applicants characterize Miwa as teaching treatment of laboratory prepared plasmid DNA with an RNaseI to remove any contaminating RNA which is present in the sample. It is asserted that Miwa "does not provide methods or procedures to address pre-existing amplicons, or similar contamination of evidentiary tissue samples that are introduced to a site or a sample to confound future analysis.

This argument has been fully considered but is not persuasive. First it is noted that Applicants are arguing limitations that are not recited in the claims. In particular, the presently rejected claims are not directed to methods for removal of "pre-existing amplicons" from tissue samples. Secondly, Applicants arguments are not convincing because the method of Miwa is in fact one in which contaminating nucleic acids that have been introduced into a sample and which confound future analysis of the sample are removed. In the method of Miwa, the sample is contaminated with RNA (i.e., a nucleic acid introduced into the sample by lysis of bacterial cells) and the RNA confounds future analysis of target plasmid DNA in the sample. Accordingly, in the method of Miwa, the contaminating RNA meets the limitations in the present claims of a contaminating nucleic acid since the RNA is introduced into the sample in the laboratory and confounds future analysis of the sample.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/

Primary Examiner, Art Unit 1634